IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re Application of McBride and Griffiths
U.S. Serial No.: 09/676,783
Filed: October 2, 2000
Attorney Docket No.: 40923-0065US2 (formerly 018733/0997)
For: RADIOMETAL-BINDING PEPTIDE ANALOGUES

REPLY

Appeal from Group 1639

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This is in reply to the Examiner's Answer mailed March 10, 2004 (Paper No. 11). Appellants do not believe that any fees are due; in the event this is not correct, the Board is authorized to debit the undersigned's account no. 08-1641.

I. THE EXAMINER'S POSITION

A. The Examiner's Rejection

The Examiner acknowledges that claims 24-40 and 42-43 meet the statutory requirement for enablement and utility. (Examiner's Answer, page 5, Section 11, first paragraph.) However, the Examiner alleges that these same claims fail to meet the written description requirement because there is not "enough written description in the specification as to the different kind of tumor(s), peptides, modes of administration, dosage and test procedures or steps in specific terms as to the treatment method." (Examiner's Answer, page 4, Section 10, third paragraph.)

The Examiner states that the specification describes "an assay method as to the supposed binding effect of the peptide LHRH or VIP analogues to breast cancer cells" (*Id.*), but alleges that no results are provided for the binding method, that it is not apparent how the assay method translates or correlates the binding effect to a treatment method and that claim 24 does not recite the peptides LHR or VIP analogues. According to the Examiner, this alleged "general statement" and "general assay method" fail to satisfy the statutory requirement for a full, clear and concise description of the claimed method. (Examiner's Answer, page 5, Section 10, last paragraph.)

B. The Examiner's Opinion

In view of the above, it appears that the Examiner's written description rejection is based upon the Examiner's belief that the claimed invention is not described "enough" or is not described "clearly" or "fully" or "concisely." However, the Examiner's true concern is a public policy one, which is clear from the following:

> To allow appellants to dominate a highly unpredictable and not fully elucidated field based on the expediency of the prophetic, generalized statement or meaningless conclusion in the specification will not promote science as intended by the law. It will bar one who has actually worked and discovered the details of the treatment method.

(Examiner's Answer, page 15, next to last paragraph)

Appellants respectfully submit that such concerns are misplaced.

II. THE LAW

The controlling law in this case is well-settled. First, there is a strong presumption that an adequate written description of the claimed invention is present in the specification as filed. *In re Wertheim*, 541 F. 2d 257, 262, 191 USPQ 90, 96 (CCPA 1976). In order to meet the written description requirement, there must be sufficient written description to inform a skilled artisan that the applicant was in possession of the invention as a whole at the time the application was filed. *See e.g. Purdue Pharma L.P. v. Faulding Inc.* 230 F. 3d 1320,1323, 56

USPQ 2d 1481, 1483 (Fed Cir. 2000); *as cited in Manual of Patent Examining Procedure* ("MPEP"), Section 2163, page 2100-165. (Rev. 1 Feb. 2003).

It does not matter that the description in the specification is prophetic. It does not matter that the claim is to a genus and only a few species are exemplified. It does not matter that applicants rely upon what is known in the art to describe the invention. It does not matter that the result is a claim that dominates others. It does not matter that others may continue research in the field of the invention and reduce to practice or discover embodiments covered by the claims. It does not matter that the Examiner does not approve of this state of the law or is concerned about the promotion of science. What matters is that the specification conveys to those of skill in the art that they were in possession of the invention.

Possession of an invention can be shown in many ways. MPEP at 2100-165. For instance, it is proper to rely upon what is already known in the art. The description need only describe in detail that which is new or not conventional. *See Hybritech v. Monoclonal Antibodies*, 802 F. 2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986).

III. THE APPLICATION OF LAW TO FACTS

Although the controlling law is well-settled, any written description inquiry is driven by the facts of an individual case. These facts include what is in the specification as well as what was known in the art at the time of the invention.

During the course of this appeal, the Examiner agreed to allow claims directed to a method of treating a tumor so long as peptides were limited to LHRH, SMS, VIP and MSH. Thus, the Examiner has conceded that the facts of this case - including the *in vitro* assays in the specification and the art relied upon in appellants' brief - show that appellants were in possession of an invention directed to a method of treating tumors, at the time of the invention. The Examiner did not challenge the correlation of the binding with the efficacy of treatment, did not question the extrapolation of *in vitro* data to *in vivo* efficacy, and did not demand explicit modes of administration, as she does now in the Examiner's Answer. Appellants declined the Examiner's offer because the evidence presented to show possession of the invention considered allowable is the same evidence that supports a claim of broader scope. Appellants believed then and believe now that the Examiner's position is insupportable.

Appellants remind the Examiner that the present claims are directed to a method of treating tumors based upon the discovery of a new method of radiolabeling peptides. The peptides, *per se*, are not the point of novelty, but rather the novel method of labeling them for a therapeutic use. The Examiner has conceded in the Examiner's Answer that appellants have taught how to make and use the generic invention (enablement) and that such generic invention is useful (utility). Thus, the Examiner does not challenge the detail by which appellants teach how to make or how to use the generic invention in the specification or

challenge the operability of the generic invention. Nevertheless, in the Examiner's Answer, the Examiner refused to give weight to the teachings of numerous articles related to the use of radionuclides for tumor therapy and cited to support the sufficiency of appellants' written description. Rather, the Examiner challenged the significance of their teachings or the sufficiency of the presented data. The Examiner's dismissal of the cited references is a simply improper and inconsistent with the Examiner's position with regard to enablement and utility.

IV. CONCLUSION

The Examiner's position in this case as reflected in the Examiner's Answer is improper and based upon a selective application of the law and a selective reading of the record. Accordingly, reversal of the rejection for lack of written description is proper and respectfully requested.

Respectfully submitted,

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